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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/082, 247      05/20/98      NADEAU

J      P-2821RI

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EXAMINER

HOUTTEMAN, S

ART UNIT	PAPER NUMBER
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1655

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DATE MAILED:

12/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 09/082,247	Applicant(s) Nadeau et al.
Examiner Scott Houtteman	Group Art Unit 1655

Responsive to communication(s) filed on Sep 28, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

- Claim(s) 1-50 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) 1-20 is/are allowed.  
 Claim(s) 21-50 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

1. Applicant's response, filed 9/28/99, has been carefully considered with the following effect:

The objection and rejections of paragraphs 2-4, Office action mailed 6/22/99, have been withdrawn in view of applicant's amendments.

The objections and rejections of paragraphs 6, 7 and 9, Office action mailed 6/22/99, have been maintained.

The objection of paragraphs 1, Office action mailed 6/22/99, has been held in abeyance.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 21-42 are rejected under 35 U.S.C. 112, first paragraph. They contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record (new matter).

4. Applicant argues, briefly that support is found for example in 6 passages and that the passage warning against the use of PCR leading to "high levels of background signal," support the "generic" description and definitions referenced above.

These arguments are not persuasive. The argument has not established why, if the discussion of amplification is generic, there is no mention of PCR coupled amplification only SDA

coupled amplification. Similarly, the argument does not address why the plain meaning of the recited passage, warning about high background when PCR is used, should be disregarded.

5. Claims 21-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record.

6. Applicant argues that "genericness of the claims is embodied in the fact that the signal primer is situated down stream of the amplification primer" and that "alleged undesirable high levels of background signal are not manifest in a primer based amplification method."

7. These arguments are not persuasive. The argument has not explained why the warnings explicit in the specification are either taken out of context or reflect some misunderstanding of the invention as disclosed in the specification. Furthermore, the fact that "undesirable high levels of background signal are not manifest in a primer based amplification method" is not the issue. The issue is that was enabled, as of the filing date, based on the disclosure of this application and what flows naturally from the disclosure.

8. Claims 43-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullis et al. US Pat. 4,683,195; 7/1987 (Mullis) or Urdea, US Pat. 5,200,314; 4/1993, for reasons of record. Applicants argument is not persuasive. The argument merely offers conclusions: the claimed

signal primer has "unique properties" of hybridizing down stream of an amplification primer. The argument does not explain how the structure of completely separate and generically defined products (the amplification primer, and a generic target nucleic acid) can, in any way, limit the structure of the claimed product.

**9. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

**10.** Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 8:30 AM - 3:30 PM. The examiner can also be reached on alternate Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman  
December 20, 1999

  
SCOTT W. HOUTTEMAN  
PRIMARY EXAMINER